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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LOEWE, SUN JAE Y	

ART UNIT	PAPER NUMBER
1626	

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08/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,283	DUFFY ET AL.	
	Examiner	Art Unit	
	Sun Jae Y. Loewe	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,26-29,31 and 33* is/are pending in the application.

4a) Of the above claim(s) *7-10,26-29 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11-23 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

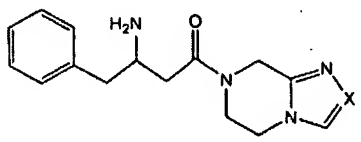
1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III in the reply filed on July 11, 2007 is acknowledged. The traversal is on the ground(s) that Groups I-IV

relate to a single inventive concept which is a class of compounds of the formula below useful for the treatment of diabetes:



. This is not found persuasive because the core structure referenced above is taught in the prior art (section 3 of the restriction requirement dated June 26, 2007). Thus, the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the special technical feature that makes a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7-10, 26-29 and 33 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter. Applicant timely traversed the restriction (election) requirement in the reply filed on July 11, 2007.

Information Disclosure Statement

3. The information disclosure statement (IDS) filed on October 17, 2005 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered. A signed copy of form 1449 is enclosed herewith.

Claim Objections

4. Claims 1-6, 11-23 and 31 objected to for containing non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 11-21, 23 and 31 rejected under 35 USC 112 1st paragraph as failing to comply with the written description requirement.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

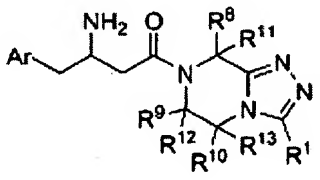
> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically states that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (ie. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3rd column, 3rd paragraph). Below is such comparison.

I. Scope of Claims (based on *elected* subject matter)

Compounds of Formula



The following variables are claimed *broader* than what is supported by the disclosure (see below section II):

R^1:	for claims 1-6, 11-21, 23 and 31
R^3:	for claims 1-6, 13-21, 23 and 31
R^4-R^6:	for claims 1-6, 11-21, 23 and 31
R^8:	for claims 1-6, 11-20, 23 and 31
R^9-R^{10}:	for claims 1-6, 11-19, 23 and 31

II. Scope of Disclosure

Reduction to Practice:

The compounds reduced to practice support the following for variables the variables noted above:

R^1: hydrogen,

halogen,

C_{1-10} alkyl, wherein alkyl is unsubstituted or substituted with one to five substituents independently selected from halogen or hydroxy,

C_{1-10} alkoxy, wherein alkoxy is unsubstituted or substituted with one to five substituents independently selected from halogen or hydroxy,

C_{1-10} alkylthio, wherein alkylthio is unsubstituted or substituted with one to five substituents independently selected from halogen or hydroxy,

C_{2-10} alkenyl, wherein alkenyl is unsubstituted or substituted with one to five substituents independently selected from halogen or hydroxy,

$(CH_2)_nCOOH$,

$(CH_2)_nCOOC_{1-6}$ alkyl,

$(CH_2)_nCONR^4R^5$, wherein R^4 and R^5 are independently selected from the group hydrogen, tetrazolyl, C_{1-6} alkyl or R^4 and R^5 together with the nitrogen atom to which they are attached form

morpholine wherein said heterocyclic ring is unsubstituted or substituted with one to five substituents independently selected from halogen, hydroxy, C_{1-6} alkyl, and C_{1-6} alkoxy, wherein alkyl and alkoxy are unsubstituted or substituted with one to five halogens;

$(CH_2)_n$-NR^4R^5,

$(CH_2)_n$-NR^7COR^7,

$(CH_2)_n$-COR^6,

R^6 is independently selected from the group consisting of $(CH_2)_n$-C_{3-6} cycloalkyl, and C_{1-6} alkyl,

$(CH_2)_n$-C_{3-6} cycloalkyl,

R^3: hydrogen,

halogen,

C_{1-6} alkyl, unsubstituted or substituted with one to five halogens

R^8-R^{10}: hydrogen,

C_{1-10} alkyl, unsubstituted or substituted with one to five substituents independently selected from halogen, hydroxy, C_{1-6} alkoxy, carboxy, C_{1-6} alkyloxycarbonyl, and phenyl-C_{1-3} alkoxy, wherein alkoxy is unsubstituted or substituted with one to five halogens,

Reduction to Structural or Chemical Formulas:

The only disclosure, in addition to the species reduced to practice, is in form of a *list* of possible substituents for each variable. This type of disclosure is not viewed to be a representation of any of the species it entails. A"laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Therefore, there is no disclosure of species (eg. by reduction to structural/chemical formulas) in addition to those reduced to practice.

Correlation between Structure and Function:

A structure/activity study (SAR) is disclosed by Kim et al. for a subgenus of the instantly claimed compounds. These studies evaluate the activity of the compounds as a function of changing the substituents to the phenyl and

triazolopyrazinyl rings (H vs. alkyl optionally substituted with halogen); however, the effect of changing R^1, R^3, R^4-R^6, R^8-^{10} to other substituents (eg. those encompassed by the instant invention) was not evaluated/reported. Furthermore, the instant specification does not disclose any correlation between function and structure. Thus, it is not understood what *specific structural elements* (pertaining to variables R^1, R^3, R^4-R^6, R^8-^{10} are *essential* or *non-essential* for the activity of the instantly claimed compounds.

III. *Analysis of Fulfillment of Written Description Requirement:*

In the absence of a correlation between structure (as it pertains to variables R^1, R^3, R^4-R^6, R^8-^{10}) and function, it is not possible to predict what modifications will allow for the preservation of the desired activity.

In conclusion: (i) substantial structural variation in the genus/subgenus embraced by claims 1-6, 11-21, 23 and 31; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of genus claimed; (iii) common structural attributes of the claimed genus, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art. Thus, the specification fails to provide adequate written description for the genus of compounds claimed and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. (i) Claims 1-6 and 11-23 rejected under 35 U.S.C. 103(a) as being obvious over Edmonson et al. (US Patent 6,699,871). See for example, preferred embodiment in column 4 and representative compound of example 7 in column 32.

(ii) Claims 1-6 and 11-23 rejected under 35 U.S.C. 103(a) as being obvious over Edmonson et al. (20060270679 publication of US Appl # 11/500,252). See for example, preferred embodiment on p. 2 and representative compound of example 7 on p. 18.

(iii) Claims 1-6 and 11-23 rejected under 35 U.S.C. 103(a) as being obvious over Brockunier et al. (20050107390 publication of US Appl # 10/508,898). See for example, compound of example 3 on page 20.

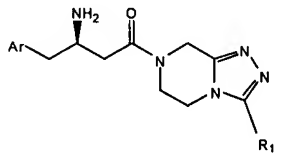
The applied references have common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed

but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

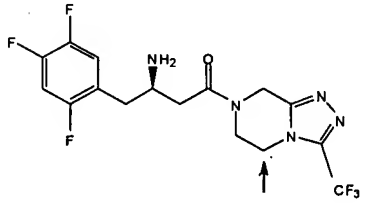
(Refer to scheme 1, below, for the Graham v. Deere analysis for i-iii)

Scheme 1

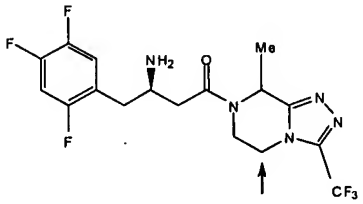
a)



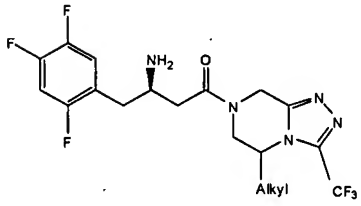
b)



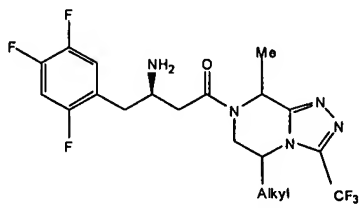
d)



c)



e)



Determination of the scope and contents of the prior art.

(i)-(ii) The references teach compounds within the genus shown in Scheme 1a, exemplified by the compound shown in Scheme 1b., and pharmaceutical compositions thereof.

(iii) The reference teaches, for example, compound of Scheme 1d and pharmaceutical composition thereof.

Ascertaining the differences between the prior art and the claims at issue.

(i)-(iii) The prior art compounds (Scheme 1a, 1b and 1d) have been excluded from the instant invention via a proviso.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

(i)-(iii) One of ordinary skill in possession of any of the three references would be motivated to make the following compounds, with reasonable expectation of obtaining the same DP-IV inhibition activity: homologs of the compounds wherein the position marked by the arrows in Scheme 1b and 1d are modified to alkyl, for example. These homologs of the H-substituted prior art compounds fall within the genus instantly claimed. Thus, based on structural similarity, the prior art suggests to one of ordinary skill in the art to make this substitution. A *prima facie* case of obviousness based on structure exists if the prior art suggest to one of ordinary skill in the art to make the substitution or modification. *In re Taborsky* (CCPA 1974) 502 F2d 775, 183 UPQ 50. To those skilled in chemical art, one homologue is not such an advance over adjacent member of a series because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). Additionally, the instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used as DP-IV inhibitors. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. Additionally, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., a DP-IV inhibitor). Thus, the instant claims are *prima facie* obvious over the teachings of the three references.

7. Claims 1-6, 11-23 and 31 rejected under 35 U.S.C. 103(a) as being obvious over Edmonson et al. (US Patent 7,125,873). See for example, preferred embodiment in column 4 and compound of example 7 in column 32.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

(Refer to scheme 1 for the Graham v. Deere analysis)

Determination of the scope and contents of the prior art.
The reference teaches pharmaceutical composition comprising compound shown in Scheme 1b (for example) and other DP-IV inhibitors.

Ascertaining the differences between the prior art and the claims at issue.
The prior art composition is excluded from the instant claims via a proviso excluding the compound of Scheme 1b.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

One of ordinary skill would be motivated to make modifications to the compounds – and ensuing pharmaceutical compositions, of Edmonson et al. to arrive at the instant invention. For example, see compound in Scheme 1c and discussion in section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in US Patent 7,125,873.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-6 and 11-23 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,699,871 (see for example, preferred embodiment in column 4 and representative compound of example 7 in column 32). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons below.

Determination of the scope and contents of claims 1-20 of U.S. Patent No. 6,699,871.
Compound within the genus shown in Scheme 1a, exemplified by the compound shown in Scheme 1b., and pharmaceutical compositions thereof.

Ascertaining the differences between claims 1-20 of U.S. Patent No. 6,699,871 and instant claims.
The compounds, and the ensuing pharmaceutical compositions, have been excluded from the instant invention via a proviso.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the compounds claimed in U.S. Patent No. 6,699,871 to arrive at compounds that are encompassed by the instant invention, for example compounds in Scheme 1c. See discussion above section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in U.S. Patent No. 6,699,871.

9. Claims 1-6 and 11-23 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-5, 9, 12, 13, 15, 16, 18, 19, 20, 21 and 42 of copending Application No. 10/508898 (2005/0107390), see for example

compound of example 3 on page 20. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Determination of the scope and contents of claims 2-5, 9, 12, 13, 15, 16, 18, 19, 20, 21 and 42 of copending Application No. 10/508898.
Compounds such as the one shown in Scheme 1d and pharmaceutical compositions thereof.

Ascertaining the differences between claims 2-5, 9, 12, 13, 15, 16, 18, 19, 20, 21 and 42 of copending Application No. 10/508898 and instant claims.
The compounds, and the ensuing pharmaceutical compositions, have been excluded from the instant invention via a proviso.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the compounds claimed in copending Application No. 10/508898 to arrive at compounds that are encompassed by the instant invention, for example, Scheme 1d. See discussion above section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in Application No. 10/508898.

10. Claims 1-6, 11-23 and 31 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,125,873 (see for example, preferred embodiment in column 4 and representative compound of example 7 in column 32). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons below

Determination of the scope and contents of claims 1-4 of U.S. Patent No. 7,125,873 .
Pharmaceutical composition comprising compounds of the genus shown in Scheme 1d, exemplified by compound in Scheme 1b.

Ascertaining the differences between claims 1-4 of U.S. Patent No. 7,125,873 and instant claims.

The prior art composition is excluded from the instant claims via a proviso excluding the compound of Scheme 1b.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the compounds – and ensuing pharmaceutical compositions, claimed in U.S. Patent No. 7,125,873 to arrive at the instant invention. For example, see compound in Scheme 1c and discussion in section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in U.S. Patent No. 7,125,873.

11. Claims 1-6, 11-23 and 31 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 8 and 13 of copending Application No. 10/559,206 (2007/0099884). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Determination of the scope and contents of claims 1-4, 7, 8 and 13 of copending Application No. 10/559,206.
Pharmaceutical compositions comprising compound (eg. Scheme 1b.) and anti-obesity/anti-diabetic (eg. DP-IV inhibitor) agents.

Ascertaining the differences between claims 1-4, 7, 8 and 13 of copending Application No. 10/559,206 and instant claims .
The prior art composition is excluded from the instant claims via a proviso excluding the compound of Scheme 1b.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the compounds – and ensuing pharmaceutical compositions, claimed in copending Application No. 10/559,206 to arrive at the instant invention. For example, see compound in Scheme 1c and discussion in section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in copending Application No. 10/559,206.

12. Claims 1-6, 11-23 and 31 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending

Application No. 11/440,198 (2006/0270722). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Determination of the scope and contents of claims 1-4 of copending Application No. 11/440,198.
Pharmaceutical compositions comprising compound (eg. dihydrogen phosphate salt of compound in Scheme 1b) and PPAR α/γ dual agonist.

Ascertaining the differences between claims 1-4 of copending Application No. 11/440,198 and instant claims .
The prior art composition is excluded from the instant claims via a proviso excluding the compound of Scheme 1b.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the structure in Scheme 1b, which is claimed in copending Application No. 10/559,206 to arrive at the instant invention. For example, see structure in Scheme 1c and discussion in section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in copending Application No. 11/440,198.

13. Claims 1-6 and 11-23 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-10, 49 and 53-60 of copending Application No. 10/569,556 (20060287528). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Determination of the scope and contents of claims 3-10, 49 and 53-60 of copending Application No. 10/569,556 and instant claims
Pharmaceutical compositions comprising dihydrogen phosphate salt of the compound in Scheme 1b; drug substance comprising dihydrogen phosphate salt of the compound in Scheme 1b.

Ascertaining the differences between claims 3-10, 49 and 53-60 of copending Application No. 10/569,556
The prior art salt is excluded from the instant invention via a proviso. The prior art composition is excluded from the instant claims via the proviso that excludes the salt.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the structure in Scheme 1b, which is claimed in copending Application No. 10/569,556 to arrive at the instant invention. For example, see structure in Scheme 1c and discussion in section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in copending Application No. 10/569,556.

14. Claims 1-6 and 11-23 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23, 25, 26, 34 and 35 of copending Application No. 10/874992 (2005/0032804). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Determination of the scope and contents of claims 1-23, 25, 26, 34 and 35 of copending Application No. 10/874992
Pharmaceutical compositions comprising dihydrogen phosphate salt of the compound in Scheme 1b; drug substance comprising dihydrogen phosphate salt of the compound in Scheme 1b.

Ascertaining the differences between claims 1-23, 25, 26, 34 and 35 of copending Application No. 10/874992 and instant claims
The prior art salt is excluded from the instant invention via a proviso. The prior art composition is excluded from the instant claims via the proviso that excludes the salt.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the structure in Scheme 1b, which is claimed in copending Application No. 10/874992 to arrive at the instant invention. For example, see structure in Scheme 1c and discussion in section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in copending Application No. 10/874992.

15. Claims 1-6 and 11-23 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-9, 11, 14 and 18-25 of copending Application No. 10/570409 (2007/0021430). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Determination of the scope and contents of claims 1, 3-9, 11, 14 and 18-25 of copending Application No. 10/570409
Pharmaceutical compositions comprising dihydrogen phosphate salt of the compound in Scheme 1b; drug substance comprising dihydrogen phosphate salt of the compound in Scheme 1b.

Ascertaining the differences between 1, 3-9, 11, 14 and 18-25 of copending Application No. 10/570409 and instant claims
The prior art salt is excluded from the instant invention via a proviso. The prior art composition is excluded from the instant claims via the proviso that excludes the salt.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.
One of ordinary skill would be motivated to make modifications to the structure in Scheme 1b, which is claimed in copending Application No. 10/570409 to arrive at the instant invention. For example, see structure in Scheme 1c and discussion in section 6 for homologous series. Thus, the instant claims are *prima facie* obvious over the claims in copending Application No. 10/570409.

Conclusion

16. No claims allowed.

17. Any inquiry concerning this communication should be directed to Sun Jae Y. Loewe whose telephone number is 571-272-9074. The examiner can normally be reached on Monday through Friday from 7:30 am to 5:00 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Joseph McKane may be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rebecca Anderson/
Primary Examiner, AU 1626